

General Navigation Guide for Manufacturers of FDA-Regulated Products and Start-ups

The general navigation guide below is provided in the event it may be helpful to companies wondering if their planned activities would be subject to regulation by FDA. An overview of products that FDA regulates can be found here (<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>).

The information below is a simplified flow chart intended to provide companies a start in contacting a relevant FDA office with questions. It should not be used to make a final decision about the regulatory status of a product. You can access the Federal Food, Drug, and Cosmetic Act and other laws FDA enforces on the FDA Web site (<http://www.fda.gov/RegulatoryInformation/Legislation/default.htm>). Title 21 of the Code of Federal Regulations is reserved for FDA rules and a database containing these rules is available on the FDA Web site (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>).

1. Is your product or product idea a drug, device, or food given to, or used on, an animal?
 - a. Yes: Visit <http://www.fda.gov/AnimalVeterinary/> and contact FDA CVM Communication Staff
 - b. No: Proceed to number 2
2. Is your product or product idea intended to cure, treat, mitigate, diagnose, or prevent disease in humans, or is your product (other than food) intended to affect the structure or function of the human body?
 - a. Yes: Does your product achieve its primary intended purposes through chemical action and is your product metabolized by the human body?
 - i. Yes: It is likely your product will be considered a human drug or a biological product. For human drug products, please visit <http://www.fda.gov/Drugs/> and contact FDA CDER Human Drug Information. For biological products, please visit <http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry/> and contact CBER Manufacturers Assistance and Technical Training Branch (MATT)
 - ii. No: It is likely your product will be considered a medical device for humans. Visit <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/> and contact FDA CDRH Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
 - iii. Yes and no, or unknown: Please visit <http://www.fda.gov/CombinationProducts/> and contact the FDA Office of Combination Products. You may wish to submit a Request for Designation (RFD) for your product or product idea.
 - b. No: proceed to number 3.
3. Is your product or product idea a food (includes dietary supplements) consumed by humans, chewing gum, or a beverage? Most meat and poultry products

(except for game meats, such as venison, ostrich, and snake) are regulated by the U.S. Department of Agriculture.

- a. Yes: For foods consumed by humans, chewing gum or beverages, please visit <http://www.fda.gov/Food/> and contact the FDA CFSAN Outreach and Information Center.
For dietary supplements, please visit <http://www.fda.gov/Food/DietarySupplements/> and contact the FDA CFSAN Outreach and Information Center. If your product contains active ingredients in FDA-approved drugs or their analogs (closely-related drugs), your product may be considered a human drug.
 - b. No: proceed to number 4.
4. Is your product or product idea a cosmetic applied to the body to cleanse or alter the appearance of the body (and does not have a Sun Protection Factor (SPF) nor is it intended for sun protection, protection against cold, wind, skin damage, dandruff, wetness (antiperspirant))?
- a. Yes: Please visit <http://www.fda.gov/Cosmetics/> and contact CFSAN Outreach and Information Center
 - b. No: Proceed to number 5.
5. Is your product or product idea made or derived from tobacco?
- a. Yes: Please visit <http://www.fda.gov/TobaccoProducts/> and contact the FDA Center for Tobacco Products
 - b. No: Proceed to number 6.
6. Does your product or product idea emit radiation of any kind?
- a. Yes: Visit <http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ucm202505.htm> and contact the FDA CDRH Radiological Health Program, Office of Communication, Education and Radiation Programs
 - b. No: Proceed to number 7.
7. Your inquiry may still be related to FDA. Please contact your nearest FDA Public Affairs Specialist or Small Business Representative for assistance. A directory of FDA offices in the field is available online at <http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm>.

FDA's responsibilities are closely related to those of several other government agencies. You can find names and contact information (<http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDADoesntRegulate/default.htm>) for government agencies that have functions related to that of FDA.